UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. WILLIAM FACTEAU, PATRICK FABIAN	Criminal No. 15-10076-ADB

GOVERNMENT'S SENTENCING MEMORANDUM AS TO WILLIAM FACTEAU

The United States submits this memorandum in support of its recommendation that the Defendant William Facteau ("Defendant" or "Facteau") be sentenced to term of six months incarceration and six months of home detention, supervised release for one year, a fine of $1,000,000 and a special assessment of $250. Such a sentence is warranted based upon the Defendant's serious criminal activity and his abuse of a position of great privilege, trust and responsibility for the health of others. It will also serve to avoid sentencing disparities by ensuring that a white-collar defendant serves jail time for a corporate crime just as many non-white collar defendants serve long sentences of incarceration for street crimes.

As the Court found, this is not a case of criminal culpability for a corporate officer merely based upon his position or job responsibilities. Here, Facteau made key decisions and directed and participated personally in the criminal violations of the federal Food, Drug, and Cosmetic Act ("FDCA"). In fact, the jury's verdict and the evidence at trial demonstrate that Facteau was not just a participant in the criminal conduct, not just aware of it, not just negligent in failing to prevent it. He was a mastermind and driver of the crimes that resulted in approximately $40 million in sales of medical devices that were adulterated and misbranded. He should be sentenced to a jail sentence in order to appropriately punish his conduct and send a clear message to other

such health care executives who seek to end-run the FDA regulatory system and its protections for the patients of this country.

I. SUMMARY OF EVIDENCE

Facteau caused illegal sales of a medical device known as the Relieva Stratus Microflow Spacer ("Stratus") for intended uses for which it had not been cleared or approved by the FDA. Stratus was a medical device for implanting a small balloon with tiny holes in the nasal sinuses. Facteau knew the Stratus was designed and intended to provide sustained delivery of drugs and, in particular, steroids, to the sinuses. He knew it did not work for the use for which Acclarent submitted it to the FDA and the use for which the FDA cleared it: as a spacer filled with saline.

From about 2008 through 2011, Facteau caused the Acclarent sales and marketing teams to sell the Stratus intending it to be used as a steroid delivery device. Even after Johnson & Johnson purchased Acclarent in 2010 and directed Acclarent to stop promoting the Stratus at all due to the extensive off-label use of the product, Facteau and Fabian continued to direct Acclarent employees to market the Stratus for use as a steroid delivery device in 2010 and 2011.

When Johnson & Johnson purchased Acclarent for $785 million in 2010, Facteau made approximately $32 million from his stock options and other compensation.

The Development of the Stratus and Distribution Strategy

Beginning in about 2005, Facteau caused Acclarent and its engineers to develop and design the Stratus to provide sustained release of the steroid Kenalog-40 in the nasal passages by designing a reservoir with a pattern of holes to try to slowly release the Kenalog-40 over an extended period of time. The Stratus, however, was not designed to work as a spacer and had no design specifications to mechanically maintain any particular space.

In August 2006, Facteau caused Acclarent to submit a 510(k) notification to the FDA requesting clearance to market the Stratus as a post-operative spacer. Based upon Acclarent's

false representations that the device was intended to mechanically maintain an opening to the sinus following surgery and could moisten the sinus with saline, the FDA concluded that the device was substantially equivalent to a legally marketed device, and cleared it to be marketed for that intended use only; i.e. to mechanically maintain an opening to the sinus.

On April 16, 2007, Acclarent asked the FDA to expand the indications for Stratus to add language that the device was "also indicated for use to irrigate the sinus space for diagnostic and therapeutic procedures." On May 21, 2007, the FDA wrote to Acclarent that such changes could not be made based upon the existing submissions and evidence and stated as follows:

> Based solely on the change or modifications that you have described, it appears that you have significantly changed or modified the design, components, methods of manufacture, device labeling or intended use of the device referenced above.

In addition, on or about December 5, 2007, the FDA determined that the study of the Stratus for Kenalog-40 delivery raised significant risks and prohibited Acclarent from continuing such a study without first seeking and obtaining FDA approval for the study.

Facteau Approves the Launch of Stratus Intending It to Be Used for Steroid Delivery Without FDA Approval or Clearance

In about January 2008, Facteau decided to launch the Stratus, even though he knew Acclarent did not have FDA clearance for the device to be used for drug delivery and intended the device to be used for drug delivery. As CEO, Facteau had final authority over whether Acclarent began to distribute the Stratus and approved the decision to launch the Stratus without FDA clearance for its intended use to deliver steroids. Under the direction of Facteau, from about February 2008 through 2011, Acclarent distributed the Stratus to physicians intending that it be used for steroid delivery and for implantation longer than 14 days, while purporting to distribute it for its FDA-cleared use as a spacer to be used with saline.

In the summer of 2008, Facteau and Fabian prepared for a full commercial launch of the Stratus and trained Acclarent's sales force and physicians to use the product as a Kenalog-40 delivery device. Facteau and Fabian directed others at Acclarent to prepare sales and promotional materials for the Stratus that did not promote it for its FDA-cleared intended use as a spacer. Instead, they promoted it to deliver a fluid to bathe the sinuses. The primary Stratus promotional brochure had a picture of the Stratus inflated with a milky white substance intended to look like Kenalog-40r. Beginning in late summer 2008, under the direction of Facteau and Fabian, Acclarent representatives shared these promotional pieces with doctors to whom they were marketing the Stratus as a steroid delivery device.

Facteau pursued this full commercial launch despite receiving objections from a physician on Acclarent Scientific Advisory Board and despite Facteau's own acknowledgement that the product was not ready. One physician wrote to Facteau and others on Acclarent's Scientific Advisory Board, objecting to the launch of the Stratus on the following grounds, among others:

> – Acclarent is marketing and making available for sale a new sinus implant for delivery of medications intended to eliminate the need for traditional surgery on the target sinus . . .
> –The device is NOT FDA approved for use with any medication,
> –The device has no efficacy data to support its use for any degree of sinus inflammation
> – The device has limited safety data derived primarily from experienced rhinologists

Facteau replied and agreed that the Stratus was not FDA-approved for use with any medication in the United States. He also conceded that the "SPACER [was] not ready for prime time." In this email exchange, Facteau also stated:

> The efficacy and indications have not yet been determined. The best way to think about this technology today is as another tool in your armamentarium to manage your surgical patients where you think they may benefit from a local dose of steroid to reduce inflammation . . .

On September 16, 2008, Facteau conducted two nationwide sales conference calls with required attendance by all Acclarent sales and marketing employees. During these mandatory conference calls, Facteau instructed the sales force to tell physicians that local drug delivery has a role in treating ethmoid disease and to position the Stratus as a more effective way to deliver an agent. The sales force was not instructed on how to sell the Stratus for its only cleared use – as a spacer with saline.

Even after Johnson & Johnson purchased Acclarent in 2010 and declared that there was to be no promotion at all of the Stratus, Fabian wrote to the sales managers and the entire sales force (copying Facteau) instructing the sales force to continue to sell Stratus and that all on-label discussions were acceptable. In that email, Fabian explained: "declining Stratus business (ignoring stratus business) has shown a strong correlation to declining core business."

II. GUIDELINES CALCULATION

A. As the Court Recognized, the Evidence at Trial Established that the Criminal Activity Involved More Than Five Participants and Was Otherwise Extensive.

The evidence at trial demonstrated that Facteau and Fabian directed the conduct for which they were convicted and that most, if not all, of the Acclarent sales force carried out the scheme. Thus, Facteau and Fabian were organizers and leaders of criminal activity that involved five or more participants and was otherwise extensive under USSG § 3B1.1(a).

The evidence showed that the Acclarent sales force of over 100 representatives and managers (GX 2533 at 28-29) was trained to sell – and did sell – the Stratus solely for a use that they knew the FDA had not cleared: as a drug delivery device with Kenalog-40.[1] As set forth

[1] *See*, *e.g.*, GX0959 (invitation to September 2008 national conference call held by Facteau and attended by Fabian where entire Acclarent sales force received direction to sell Stratus as drug delivery device); GX2550_001 (Facteau's notes for September 2008 national

below, numerous sales representatives and managers testified that their managers trained them to sell the Stratus only for steroid delivery and that they did just that even though they knew the Stratus did not work for its FDA-cleared use as a spacer with saline:

- Molly Vanderkarr, sales representative and manager: 5 Trial Tr. 123-24 (she understood a manufacturer may sell products only for cleared/approved uses, she never sold Stratus for its cleared intended use); 5 Trial Tr. 143-44 (she did not want to put her off-label discussions in writing because she knew they were wrong; for this reason, she told sales representative Jason Elmore to remove the word "drug" from an email, while still intending the same message); 6 Trial Tr. 15-17 (sales talk by sales representative Tim Steele recommended the Stratus as steroid delivery device and was discussed as successful in calls with Fabian); 7 Trial Tr. 35-37 (she sold more than $1 million of Stratus); 7 Trial Tr. 49-50 (she did not sell the Stratus solely for its FDA-cleared indication); 7 Trial Tr. 61-63 (no one in the sales force followed regulatory training in selling Stratus; throughout time she sold Stratus, she encouraged doctors to use it with Kenalog-40).

- Kevin Convery, sales representative and trainer: 8 Trial Tr. 203, 9 Trial Tr. 17 (the Acclarent R&D team, including Dan Latimer, Dan Harfe and/or John Chang, described the device to doctors as a drug delivery device,); 9 Trial Tr. 32-35 (he prepared sales material that discussed the Stratus's use for drug delivery and shared that presentation with physicians, other sales representatives, and managers [GX----]).

- Barbara Logan, sales representative: 10 Trial Tr. 66 (she never recommended Stratus for FDA-cleared use); 10 Trial Tr. 72 (she understood it was designed for bathing w/ Kenalog).

- Bradford Ader, sales representative: 11 Trial Tr. 11:34 (he never sold Stratus for cleared or approved intended use, his sales training was inconsistent with the regulatory training); 11 Trial Tr. 37, 59 (Fabian rode with him on sales calls; he followed Fabian's direction to sell Stratus for medical management / drug delivery, the direction from management was to sell the device for drug delivery).

- Norman Bilsbury, sales representative: 11 Trial Tr. 74 (he understood Stratus was designed for use with Kenalog, this was a consistent message in training and in sales presentation known as FESS by the Numbers that Elmore created and taught to sales representatives); 11 Trial Tr. 85 (he used the FESS by Numbers presentation to sell Stratus for drug delivery and it improved his business); 11 Trial Tr. 90-95 (he heard the "Total Ostomy" sales presentation that Tim Steele created and that sold Stratus for drug delivery [GX2284 (transcript of Steele "Total Ostomy" talk); GX2283_001 (audio of Steele Total Ostomy talk discussing Stratus as a drug delivery device)].

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conference call about using Stratus with Kenalog-40 to provide "an opportunity for a pharmacological approach").

- Eric Krinsky, sales representative: 10 Trial Tr. 24-26; 33-34 (the Acclarent sales training staff, including Fabian and other managers, "taught" the sales reps that the Stratus was intended to be used with Kenalog; he was not taught that the Stratus had any clinical benefit as a spacer; he was taught that the "selling point" of the Stratus was "targeted medical therapy" with Kenalog-40; no one at Acclarent told him Stratus had clinical benefit as a spacer with saline).

- Benjamin Steffen, sales representative: 7 Trial Tr. 87 (he was never trained about any clinical benefit of Stratus as a spacer and knew that saline "came right out").

While the testimony from just these seven witnesses shows that the criminal activity involved more than five participants and was otherwise extensive, the evidence at trial showed that the scheme was far broader: the ***entire Acclarent sales force*** understood from Defendants Facteau and Fabian that they were to sell the Stratus as a drug delivery device – a use for which they knew it was not FDA-cleared. And, in accordance with that understanding, the sales force sold it only for that use. As the Court recognized in its ruling denying the Defendants' motion for acquittal, "[a]t a training for new sales representatives in August 2008, Defendant Facteau gave a presentation that indicated that the company was seeking to commercialize an 'advanced drug delivery' treatment, referring to the Stratus." *See United States v. Facteau*, 2020 WL 5517573, at *7 (D. Mass. Sept. 14, 2020). The Court highlighted the two September 2008 conference calls that Defendant Facteau held with Fabian for all of Acclarent's sales representatives to discuss the "national launch of the Stratus" and quoted from the notes Facteau prepared for the call showing that he "planned to tell the sales team to talk to physicians about using the [Stratus] with Kenalog-40 in order to provide physicians with the 'opportunity for a pharmacological approach' to treating sinusitis" *See Facteau*, 2020 WL 5517573, at *7. The evidence at trial also included a lengthy audio recordings and various sales scripts that

managers Jason Elmore and Tim Steele and other sales representatives used to sell the Stratus as a steroid delivery device.[2]

Based upon the evidence at trial, the Court ruled that the Government had established a conspiracy by a preponderance of the evidence and that the defendants were members of the conspiracy. The Court further held that the statements of at least four other Acclarent employees working under Facteau and Fabian were admissible under *United States v. Petrozziello*, 548 F.2d 20 (1st Cir. 1977) because they were made during, and in furtherance of, the conspiracy: (1) Dan Harfe, an Acclarent marketing manager, 21 Trial Tr. 9-10; (2) Matt Salkeld, Director of Western Sales for Acclarent, *id.* at 21-22, (3) Jason Elmore, sales representative and manager, *id* at 24-25, and (4) Timothy Steele, sales representative and manager, *id.* at 27-28. Thus, based upon the Court's ruling as to these four co-conspirators alone and the jury's findings as to the two defendants, there were more than five participants in the criminal activity.

[2] GX0001 (Elmore's FESS by the Numbers presentation); GX1425.001-002 & 1423 (Audio recording of FESS by the Numbers). The Defendants endorsed these presentations and thus Acclarent sales force used them. *See e.g.* 5 Trial Tr. 159-160 (Vanderkarr: put her name on Elmore's slides to use with a surgeon for a presentation); 7 Trial Tr. 122-123 (Steffen: regional managers encouraged the sales representatives to "get in front of [Elmore] … to learn from him" and Fabian specifically wrote emails about Elmore's approach, which included telling surgeons how to use the Stratus as a drug delivery device; Elmore wanted representatives he supervised to use FESS by the Numbers, and the presentation was widespread in other territories); 10 Trial Tr. 48-41 (Krinsky: testifying that his manager, Jason Elmore, wanted "all of his reps" to study Elmore's "Fess by Numbers" presentation – which touted the use of Stratus as a drug delivery device – so that they could give it to customers); 11 Trial Tr. 84-85 (Bilsbury: gave FESS by the Numbers presentation more than once and it improved his business); GX2284 (transcript of Steele "Total Ostomy" talk); GX2283_001 (audio of Steele Total Ostomy talk which discussed using the Stratus as a drug delivery device).

The Court's decision denying Defendants' Rule 29 and 33 motions also reflected that the evidence showed that far more than five individuals participated in the criminal conduct. *See Facteau*, 2020 WL 5517573, at *7-12. The Court's opinion noted, among other things, that:

- Sales representative Molly Vanderkarr testified that she and another sales representative demonstrated for the entire sales force how to market the product for use as a drug delivery device with a mock presentation to a doctor – for which she received praise from Facteau. *Id.* at *8.

- Sales representative Kevin Convery testified that he "gave a presentation at that sales meeting, attended by Defendant Facteau, in which he discussed marketing the Stratus as a drug delivery device." *Id*. at *8

- "Several Acclarent sales representatives, including Ader, Convery, Barbara Logan, and Vanderkarr, testified that they never trained physicians to use the Stratus with saline and did not promote the device to physicians for use with saline [its sole FDA-cleared use]." *Id.*

- "[Acclarent sales representatives] Ader, Convery and Vanderkarr testified that they had never recommended that a physician use the device simply as a spacer, without saline or Kenalog." *Id.* at *9.

- Dr. Peter Hwang testified that sales representative Sean Riley discussed using the Stratus with steroids and never recommended using it with saline or as a spacer. *Id.*

- Dr. Armstrong testified that, at physician training sessions that Acclarent trainers gave, Acclarent trainers instructed physicians to use the device by filing it with Kenalog-40, not saline. *Id.* at *10.

- Sales representative Vanderkarr testified that she used the company-provided slides while discussing Kenalog-40 with the physicians. *Id.* at *11.

- Sometime in 2011, sales representative Benjamin Steffen saw a sales representative, Jason Elmore, give a presentation to physicians that included slides Elmore created (without going through the marketing review process) that described the Stratus as designed to elute Kenalog-40." Defendant Fabian communicated with sales representatives, including Steffen, via email, praising Elmore's sales methods. Elmore was later promoted to Director of Education and Sales for Acclarent. *Id.*

- In December 2008, Vanderkarr was on an email chain with Defendants Fabian and Facteau in which Fabian praised her for communicating with a physician about using the Stratus with Kenalog-40. *Id.*

The Court also concluded: "The Government provided ample evidence of promotional activities directed specifically at Massachusetts physicians and more nationally regarding the use of the Stratus for drug delivery." *Id.* at *19.

Facteau's offense level, therefore, must include the four-level enhancement because there were five or more participants in the criminal activity for which the defendants were convicted and of which they were organizers and leaders. *See United States v. Chin*, 965 F.3d 41 (1st Cir. 2020) (vacating sentence where court did not include four-point enhancement for pharmacist who participated in corporate FDCA scheme).

This enhancement also applies because the criminal activity was otherwise extensive. Most of the 100-plus employees at Acclarent were involved in distributing 30,000 or more Stratus devices over a period of several years. *See* USSG § 3B1.1, Application Note 3 (noting that, "in assessing whether an organization is 'otherwise extensive,' all persons involved during the course of the entire offense are considered. Thus, a fraud that involved only three participants but used the unknowing services of many outsiders could be considered extensive."); *United States v. Arbour*, 559 F.3d 50, 53 (1st Cir. 2009) (The disjunctive language of § 3B1.1(a) is important --- a criminal activity may be extensive even if does not involve five or more participants).

B. Because Facteau Used his Position of Trust to Carry Out the Crimes, a 2-Level Enhancement Under USSG § 3B1.3 Is Required.

Facteau's crimes of conviction also involved abuse of a position of trust under USSG § 3B1.3. Facteau, as the CEO, had final authority over whether Acclarent began to distribute the Stratus and approved the decision to launch the Stratus without FDA clearance for its intended use as a steroid delivery device. *See, e.g., Facteau*, 2020 WL 5517573, at *7-9. He thus used his senior executive position and managerial discretion to carry out these crimes.

Application Note 1 to § 3B1.3 defines a position of public or private trust as "characterized by professional or managerial discretion (i.e. substantial discretionary judgment that is ordinarily given considerable deference)" and notes that "[p]ersons holding such positions ordinarily are subject to significantly less supervision than employees whose responsibilities are primarily non-discretionary in nature." *Id.* Facteau abused his position as a leader of a medical device company that sold devices to be surgically implanted into people's skulls, adjacent to their brains. In holding such positions of trust, Facteau was obligated to protect public health—not just his company's profits.[3] The First Circuit has made clear that such conduct constitutes an abuse of a position of trust under USSG § 3B1.3. *See United States v. Gonzalez-Alvarez*, 277 F.3d 73, 81-82 (1st Cir. 2002) (reversing failure to include abuse of position of trust enhancement for person who sold adulterated milk in violation of FDCA). The Court explained:

> [W]e consider relevant to a § 3B1.3 inquiry whether the public expects that people in the position of the defendant will comply with health and safety regulations for which they are responsible. … The public was entitled to have dairy farmers like Gonzalez–Alvarez provide milk to processing plants compliant with all FDA and ORIL regulations, and accordingly we conclude that the defendant occupied a position of public trust.
>
> Gonzalez–Alvarez provided contaminated milk to Tres, intending that it reach the public in its adulterated state. It is clear from the record that his position as an ORIL-licensed dairy farmer significantly facilitated his commission of this offense. *See* U.S.S.G. § 3B1.3. We therefore hold that Gonzalez–Alvarez abused the position of public trust with which he was entrusted, and that the district court should have applied a 2–level enhancement pursuant to § 3B1.3.

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[3] *See also United States v. Stella,* 591 F.3d 23, 27-29 (1st Cir. 2009) (upholding abuse of trust enhancement where nurse had discretion and unsupervised access to drugs); *United States v. Pruett*, 681 F.3d 232, 248-49 (5th Cir. 2012) (applying § 3B1.3 enhancement to president and chief executive officer of waste water treatment company for environmental crime on ground that use of position facilitated the commission or concealment of the offense because he had discretion to decide what efforts were taken to comply); *United States v. Bracciale*, 374 F.3d 998, 1005 (5th Cir. 2004) (holding that defendant who was regional sales manager at Kraft Foods "occupied a position of private trust at Kraft" and "that his position of private trust significantly facilitated the commission of the offense").

Id. (citations omitted). Here, likewise, Facteau abused his position of both public and private trust by distributing the adulterated and misbranded Stratus.

Finally, the Court concluded that the evidence established the Defendants' guilt through their personal and direct participation in the illegal conduct. *Facteau*, 2020 WL 5517573, at *18, FN 140 ("This Court, however, does not need to grapple with the limits of *Park* and strict liability in the context of this case because the evidence here ***clearly demonstrated*** that ***defendants directly and personally participated in the charged conduct***." (emphasis added)). Because Facteau used his position of both public trust (as to public health) and private trust (as a senior manager of Acclarent) to carry out the crimes, a two-point enhancement under § 3B1.3 is required.

C. Final Calculation of Guidelines

The correct calculation under the Sentencing Guidelines, therefore, is as follows:

(i) in accordance with USSG § 2N2.1, Defendant's base offense level is 6 because the offenses of conviction involved violation of Statutes and Regulations Dealing with Any Food, Drug, Biological Product, Device, Cosmetic, Agricultural Product or Consumer Product;

(ii) in accordance with USSG § 3B1.1(a), Defendant's offense level is increased by 4, because defendants were organizers and leaders of criminal activity that involved five or more participants or was otherwise extensive; and

(iii) in accordance with USSG § 3B1.3, Defendants' offense levels are increased by 2 because defendants abused of positions of public or private trust or special skill.

Defendant's total offense level, therefore, is 12 or 10-16 months.

III. APPLICATION OF GUIDELINES AND SECTION 3553(a) FACTORS

The Guidelines "serve as the starting point for the district court's decision and anchor the court's discretion in selecting an appropriate sentence." *Molina-Martinez v. United States*, 136 S. Ct. 1338, 1349 (2016). Once the sentencing court has established the Guidelines Sentencing Range (including a consideration of any applicable departures), it must then evaluate the

sentencing factors set out in 18 U.S.C. § 3553(a). *United States v. Dixon*, 449 F.3d 194, 204 (1st Cir. 2006). These factors support a term of incarceration here.

A. Nature, Circumstances, and Seriousness of the Offenses

Defendant's crimes are serious and significant. He was a President and Chief Executive Officer of a medical device company – and a company that sold a product for implantation in the head, next to the brain. Preserving the effectiveness and integrity of the premarket clearance and approval processes for medical products serves an important governmental interest in protecting public health and safety. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 369 (2002). The FDCA of 1938, which introduced the requirement that firms demonstrate a product's safety before distributing it, followed the deaths of approximately 100 people from ingesting "Elixir Sulfanilamide," in which the lethal substance diethylene glycol was used as a solvent. The 1962 drug amendments, which require a showing of effectiveness, were precipitated in part by the distribution in the U.K. of thalidomide, a medication used to treat morning sickness in pregnant women that caused birth defects in their children. *See* Wallace F. Janssen, Outline of the History of U.S. Drug Regulation and Labeling, 36 *Food Drug Cosm. L.J.* 420 (1981).

The Medical Device Amendments of 1976 were also a response to public health tragedies, including from the Dalkon Shield intrauterine contraceptive device (IUD). *See* H.R. Rep. No. 94-853, at 8 (1976) (listing reports of at least 16 deaths, 25 miscarriages, and many cases of pelvic perforation from IUD). Such events also included significant defects in cardiac pacemakers that led to 34 voluntary recalls of 23,000 units, and serious side effects following implantation of intraocular lenses, including vision impairment and the need to remove some patients' eyes. *Id.* Beyond the direct harms sometimes caused by medical products, the lost opportunity to select an effective treatment for the underlying disease is itself a harm that often cannot be fully remedied after it is incurred.

There is also a substantial government and public interest in generating robust data that supports safety and effectiveness of medical products and in ensuring that diagnoses and treatment decisions are based upon reliable and accurate data from clinical trials. An incomplete, biased, or manipulative presentation to gain clearance or approval may lead to unsafe, ineffective, or unnecessary use of medical products. If companies can evade premarket review and market an unapproved product or an approved/cleared product for an unapproved use, companies will lack an adequate incentive to conduct the necessary research and trials.

The law imposes special duties and requirements on manufacturers of medical products because they create the risks and have knowledge or the ability to acquire knowledge relevant to product risk. *See Dotterweich*, 320 U.S. 277, 285 (1943); *United States v. Park*, 421 U.S. 658, 672 (1975) ("The requirements of foresight and vigilance imposed . . . are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."). Defendants' conduct in this case imperiled these important government interests and makes imposition of a jail sentence appropriate.

B. History and Characteristics of the Defendant

Facteau enjoyed great opportunities in his life. Unlike many criminal defendants whose actions are motivated by financial need or addiction or other hardships, Facteau had choices. Nonetheless, he chose a path of greed. Rather than playing by the rules, Facteau skirted the FDA medical device approval system to advance his own interests and those of his company. He used his position to vault himself and his company to overnight success and a quick payout.

Facteau led his start-up company to quick revenues and ultimately sold it off for millions, pocketing approximately $32 million. But the reason he was able to command such a high price was that he chose to find a way around the FDA regulatory system that other medical device

companies must abide by, putting patients at risk in the process. When a person of such privilege, opportunity and responsibility takes advantage of their position for no reason other than to make millions, a jail sentence is merited and necessary to send an appropriate message.

C. Need to Promote Respect for the Law and Just Punishment

The laws governing the approval and clearance of drugs and medical devices in this country are designed to protect the public from unsafe and ineffective products. These laws depend, however, upon a system of honesty with the regulators in which entities seeking to sell such products are required to cooperate with the government. It is vital that when senior executives of the entities who distribute drugs and medical devices are non-compliant and deliberately seek to evade and deceive that process, that they are appropriately punished.

Failure to sentence Facteau – the executive who led and implemented a scheme to cheat the FDA medical device approval system and carried it out for several years – to a term of incarceration would send the wrong message: "that would-be white-collar criminals stand to lose little more than a portion of their ill-gotten gains and practically none of their liberty." *United States v. Martin*, 455 F.3d 1227, 1240 (11th Cir. 2006). It is important both to "the deterrence of white-collar crime (of central concern to Congress), and "the minimization of discrepancies between white- and blue-collar offenses, and limits on the ability of those with money or earning potential to buy their way out of jail." *United States v. Mueffelman*, 470 F.3d 33, 40 (1st Cir. 2006) (cited and quoted with approval in *United States v. Levinson*, 543 F.3d 190, 197-201 (3d Cir. 2008) (noting that "probationary sentences for white-collar crime raise concerns of sentencing disparities according to socio-economic class").[4] In a legal system that

[4] *See United States v. Sample*, 901 F.3d 1196, 1198-1201 (10th Cir. 2018) (vacating where white-collar defendant sentenced to probation to allow him to work and repay victims as impermissibly sentencing based on the defendant's income); *United States v. Kuhlman*, 711 F.3d

imposes significant terms of incarceration for non-white collar crimes especially, fairness and a just system of punishment require a term of incarceration here.

D. Need to Afford Adequate Deterrence

Meaningful sentences that through their terms speak loudly are necessary to deter conduct such as Facteau's. Lenient sentences for individuals who, like Facteau, decline to play by the rules create the perception that one can take the easy road to millions and risk only a slap on the wrist. Appropriate punishment for Facteau will provide general deterrence for those who would seek to violate the laws that protect the public from unproven or unsafe medical devices. This in turn helps protect consumers from such corporate executives who would seek to abuse their positions in the critically important area of medical devices and drugs. Absent such deterrence, others with the means and opportunity to enrich themselves at the risk of patients and medical consumers, as well as our healthcare payment system, will similarly and cynically conclude that the potential rewards of such criminal activity outweigh the risks of being caught and punished. The sentence in this case should send a strong message to would-be cheats that a term of imprisonment is a reality for deliberately going around the FDA regulatory system. The sentence should also assure law-abiding market-participants that they are not foolish for playing by the rules and running the necessary clinical trials and undergoing the necessary approval

1321, 1329 (11th Cir. 2013) ("The Sentencing Guidelines authorize no special sentencing discounts on account of economic or social status."); *United States v. Prosperi*, 686 F.3d 32, 47 (1st Cir. 2012) ("[I]t is impermissible for a court to impose a lighter sentence on white-collar defendants than on blue-collar defendants because it reasons that white-collar offenders suffer greater reputational harm or have more to lose by conviction."); *United States v. Stall*, 581 F.3d 276, 286 (6th Cir. 2009) ("We do not believe criminals with privileged backgrounds are more entitled to leniency than those who have nothing left to lose."); *United States v. Stefonek*, 179 F.3d 1030, 1038 (7th Cir. 1999) ("Business criminals are not to be treated more leniently than members of the 'criminal class' just by virtue of being regularly employed or otherwise productively engaged in lawful economic activity."). *Cf.* 28 U.S.C. § 994(d)(11) (requiring that the Commission "shall assure that the guidelines and policy statements are entirely neutral as to the race, sex, national origin, creed, and socioeconomic status of offenders").

processes before distributing their products for new medical uses.

E. The Need to Avoid Unwarranted Sentence Disparities Among Defendants Guilty of Similar Conduct

The legislative history of the Sentencing Reform Act of 1984, which created the United States Sentencing Commission, made clear that one of the Act's goals was to rectify the serious problem in the criminal justice system that white-collar offenders were not being adequately punished. *See* S. Rep. No. 98-225, at 77 (1983) ("[S]ome major offenders, particularly white-collar offenders . . . frequently do not receive sentences that reflect the seriousness of their offenses."). Then-Judge Breyer, an original member of the Sentencing Commission, explained:

> The Commission found in its data significant discrepancies between pre-Guideline punishment of certain white-collar crimes, such as fraud, and other similar common law crimes, such as theft. … To mitigate the inequities of these discrepancies, the Commission decided to require short but certain terms of confinement for many white-collar offenders, including tax, insider trading, and antitrust offenders, who previously would have likely received only probation.

See Stephen Breyer, *The Federal Sentencing Guidelines and the Key Compromises Upon Which They Rest*, 17 Hofstra L. Rev. 1, 20-21 (1988). The need to avoid disparities in sentencing and the gulf between white collar sentences and non-white collar sentences calls strongly for a sentence of incarceration here, where a top executive of a health care company chooses to deliberately undermine the FDA regulatory device clearance system.

A sentence of incarceration for a misdemeanor conviction is consistent with sentences in other cases, including many with far less evidence of personal and direct knowledge and involvement by the corporate official. For example, in 2011, four corporate executives received jail sentences ranging from five to nine months for FDCA misdemeanors for distribution of adulterated and misbranded devices, notwithstanding the executives' assertions that they lacked

knowledge of relevant wrongdoing. [5] The Court rejected the defendants' arguments in that case that they should not be sent to jail because they did not know that their conduct was illegal. *United States v. Higgins*, 2011 WL 6088576, at *1 (E.D. Pa. 2011). Similarly, in October 2020, the former chief executive officer of Indivior was sentenced to six months imprisonment for Indivior's marketing of an opioid-based product without any direct involvement in the illegal acts. *United States v. Thaxter*, 20-CR-00024, Dkt. 55 (W.D.V.A. Oct. 22, 2020). *See also, e.g., United States v. Quality Egg*, LLC, 99 F. Supp. 3d 920, 942-946 (imposing three-month prison sentences based upon responsible corporate officer liability for distribution of adulterated eggs adulterated without evidence of defendants' knowledge of the contaminated eggs), *aff'd. United States v. DeCoster*, 828 F.3d 626, 631 (8th Cir. 2016).[6]

The prospect of jail time for such violations is not new or merely recent. Since the enactment of the FDCA, a great number of defendants have received custodial sentences for such

[5] *United States v. Bohner*, No. 2:09-cr-403 (E.D. Pa. Dec. 13, 2011) (eight-months); *United States v. Higgins*, No. 2:09-cr-403, 2011 WL 6088576, at *13-14 (E.D. Pa. Dec. 7, 2011) (nine months); *United States v. Huggins*, No. 2:09-cr-403 (E.D. Pa. Nov. 21, 2011) (nine months); *United States v. Walsh*, No. 2:09-cr-403 (E.D. Pa. Nov. 22, 2011) (five months).

[6] *See, e.g., United States v. Haga*, 821 F.2d 1036 (5th Cir. 1987) (ninety-day sentence for misdemeanor distribution of misbranded drugs); *United States v. Cohen*, FDA Notices of Judgment--Food ("F.N.J.") No. 26,766 (D.N.J. 1959) (three-month sentence, upon revocation of suspended sentence, for shipping adulterated eggs); *United States v. Hohensee*, 243 F.2d 367 (3d Cir. 1957) (year-and-a-day sentence for strict-liability felony distribution of misbranded drugs; *V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir. 1957) (one-year sentence for distributing misbranded food and drugs); *United States v. Kaadt*, 171 F.2d 600 (7th Cir. 1948) (one-year sentences against responsible corporate officers for distributing misbranded drugs); *United States v. Catania Importing Co.*, F.N.J. No. 7876 (D. Mass. 1945) (three-month sentence against treasurer/manager of corporation for adulteration and misbranding of oil); *United States v. Robinson*, F.N.J. No. 9695 (N.D. Ohio 1946) (six-month sentence for adulteration and misbranding of cocoa); *United States v. New Essential Cheese Cake Co.*, F.N.J. No. 4919 (E.D.N.Y. 1943) (three-month sentences against corporate officers for shipment of adulterated cheesecake); *United States v. Maltese*, F.N.J. No. 4480 (E.D.N.Y. 1942) (three-month sentence for adulteration and misbranding of oil). FDA Notices of Judgment are available at https://ceb.nlm.nih.gov/fdanj/.

misdemeanor violations.[7] Nor are custodial sentences for such offenses limited to violations of the FDCA.[8] Where, as here, defendants were directly involved in – initiated and drove the wrongdoing, such a sentence is particularly deserved and necessary.

CONCLUSION

Facteau made a deliberate choice to take advantage of the United States health care and medical device clearance system. He tried to cheat patients, doctors and payors by making them purchase this device to slowly elute a drug when he knew it had not been tested to determine whether it could deliver the drug over the promised time period, let alone FDA cleared for such use. "[T]he public has a right to expect" a heightened degree of foresight and care from "those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them." *Park*, 421 U.S. at 672. The harm here is the potential to undermine the FDA approval process and thus both the safety and efficacy of drugs and devices and the public's confidence in drugs and devices. As has been

[7] *See, e.g., United States v. Shapiro*, 491 F.2d 335, 336-37 (6th Cir. 1974) (per curiam) (upholding probation revocation and six-month sentence against company president who failed to remedy "unsanitary conditions in a vermin infested plant"); *Rich v. United States*, 389 F.2d 334, 335 (8th Cir. 1968) (affirming misdemeanor conviction and one-year sentence for sale of unlawful drugs); *United States v. Siler Drug Store Co.*, 376 F.2d 89, 89 (6th Cir. 1967) (per curiam) (affirming one-year sentence for company president and employee for selling misbranded drugs); *Lelles v. United States*, 241 F.2d 21, 23 (9th Cir. 1957) (affirming eighteen-month sentence for owner of company that distributed adulterated food and committed prior misdemeanor); *United States v. Kocmond*, 200 F.2d 370, 374 (7th Cir. 1952) (affirming nine-month sentences against individuals for selling misbranded horse meat); *United States v. Greenbaum*, 138 F.2d 437, 438 (3d Cir. 1943) (noting three-month sentence against corporate president for misdemeanor of selling rotten eggs).

[8] *See, e.g., Tart v. Massachusetts*, 949 F.2d 490 (1st Cir. 1991) (upholding, against constitutional challenge, jail sentence for strict-liability offense of unloading fish without a permit); *McQuoid v. Smith*, 556 F.2d 595, 597-99 (1st Cir. 1977) (upholding one-year sentence for strict-liability offense of possession of unregistered firearm); *Rogers v. United States*, 367 F.2d 998 (8th Cir. 1966) (upholding conviction, with ninety-day sentence, for strict-liability violation of Migratory Bird Treaty Act).

demonstrated recently again in the current pandemic, the integrity and credibility of the FDA review process is life-saving important.

The facts of this case are so clear and blatant that they did not leave the jury, nor the Court, with any reasonable doubt as to these Defendants' guilt for their own participation in, and direction of, this criminal activity. Facteau was not just a responsible corporate officer – he was a mastermind of the criminal conduct, its leader – who drove the rest of his company and its employees into the illegal conduct. He is fully deserving of the meaningful but reasonable prison sentence recommended by the United States.

Respectfully submitted,

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Dated: January 6, 2021

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

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